# EXHIBIT 42

DEPARTMENT OF HEALTH & HUMAN SERVICES

# Memorandum

Date: September 18, 1986

Refer to: DPO-R6-3:NS
DR 15

From: Health Care Financing Administration
Region VI - Dallas

Subject: Limits on Payments for Drugs - Proposed Rule
File Code BERC-356-P

To: Director
Bureau of Eligibility, Reimbursement and Coverage
Attention: BERC - 356-P



We are submitting the following comments regarding the proposed rule on limits on payments for drugs:

GENERAL

1. We support the requirement that alternative methodologies and assurances must be in the approved State Plan.

2. The State of Texas has implemented stringent EAC policies and has not experienced a drop in provider participation. The State of Washington has not experienced any loss of providers and implemented an aggressive EAC program several years ago. Therefore, we believe provider non-participation may not be as big a problem as projected.

3. The proposal indicates that there is a minimum of insurance subsidy. We are not sure what is meant by "minimum". On the average, about 20 percent of a pharmacist's business is third party pay (Drug Topics - June 1984). Generally, third party payment is fast and lucrative for pharmacists. In Massachusetts and Michigan for example, almost 50 percent of pharmacies' business is third party pay.

4. The flexibility allowed States under CIP would require additional Federal oversight to assure that aggregate limits are not exceeded if States choose a mixture of reimbursement patterns including CIP. CIP would be labor intensive on both States and HCFA from this standpoint.

PHARMACISTS' INCENTIVE PROGRAM (PhIP)

1. Reimbursement will continue to be based on the average wholesale price (AWP) even though the lowest AWP is utilized. Depending on the drug, the AWP is highly inflated above what the drug actually costs the pharmacist. This is especially true for generic drugs. This proposal would add 150 percent of an already inflated AWP to the amount which would be reimbursed by Medicaid. Also, the use of the AWP is a process which is too easily manipulated by the industry.

2. PhIP does not consider State laws on substitution of drugs.

COMPETITIVE INCENTIVE PROGRAM (CIP)

1. "Retail price" needs to be defined. Our experience has shown that retail prices are not stable because pharmacists operating in the retail market charge various prices for the same drug/same quantity to different customers, as demonstrated by usual and customary charge (UCC) reviews. There are two factors among several that pharmacists view as important in setting retail prices (a) competitive flexibility - i.e., ability to change pricing depending on whether the product is slow-turnover, price leader, discount or "full-margin" price; and (b) optimum return on investment. Consider also that retail price in most cases exceeds AWP (suggested list price).

2. The CIP alternative is not specific on the levels of discounts which would be applied. As soon as you start considering "a small discount or fee screen" you get into the same bind as we now face, i.e., "What should be the difference between AWP and actual cost from a reimbursement standpoint?"

3. CIP would require States to build and maintain UCC profiles as well as prevailing screens by locality. This would generate tremendous administrative costs above the costs now incurred by States for pricing drugs. Texas estimates that it would require eight professional people plus support staff four years to implement CIP (i.e., define policy, collect pricing data, computer transition, hold workshops for providers, etc.) in that State.

4. We do not believe five to ten percent off retail is consistent with common trade practices. This is shown in the OIG's report as well as reviews conducted by HCFA Regional Offices nationally. Is the five to ten percent discount based on a study? The discount should be based on data already collected and should be more reflective of what the pharmacist pays for a drug product.

5. The mandatory discount of 25 percent off the retail price of brand name drugs for reimbursement of multi-source drugs is insufficient. Data exist which reveal that generic drugs are marked up anywhere from 25 to 150 percent.

6. The article states that mark-ups on both brand name and generic drugs are similar. This is not true. As stated above, reviews have shown that mark-ups on these drugs vary drastically.

7. Most States do not do UCC audits as required by regulation. The elimination of survey costs, for example, announces that we accept whatever the market will bear. While screens are computationally simple, obtaining the information to develop the screens is a tremendous labor intensive task and the volume is enormous. Also, States do not generally collect data on UCC as assumed here. Not all States require providers to bill the UCC.

8. By basing payment on retail prices, CIP might in some instances encourage pharmacists to increase their prices to the general public to obtain optimum Medicaid reimbursement.

9. The reimbursement requirements for CIP are not as simple as appears in this proposal. As an example, verification of true retail prices would be extremely labor intensive. Retail pricing is complex and varied.

10. If a State believes the profit margin on retail prices under CIP is unacceptably high, there is no provision to curb reimbursement.

DISPENSING FEES

Under each of the three proposals, dispensing fees have not been specifically addressed. We believe the fee setting guidelines contained in 42 CFR 447.333 results in inconsistent and sometimes illogical fee setting methods and unjustified fee increases.

As requested in the proposed rules, I am submitting comments on dispensing fees in the form of the attached option paper.

If you have any questions, please let me know.

J. D. Sconce
Regional Administrator

Attachments